REMARKS

Claim 34 has been amended to recite, *inter alia*, that the "first domain is disposed on at least a portion of [the] interface tip." Support for this amendment may be found in the specification, for example, on page 16, lines 8-13 ("sensor interface capsular attachment layer") and Figures 1A-C. Claim 38 has been amended to recite, *inter alia*, that "at least a portion of [the] sensing membrane extends beyond the outside of the housing." Support for this amendment may be found in the specification, for example, on page 13, lines 16-22 and Figures 1A-C. Claims 33-42, 48-49, and 54-87 remain pending in the application. The Applicants have carefully considered all of the pending rejections, but respectfully submit that the claims are allowable for at least the following reasons.

Rejections under § 102

Claims 33-36, 38-42, 48, 54-58, 62-65, 70-73, 76-79, and 85-87 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 92/13271 (Rhodes). The Examiner noted that Rhodes discloses that a coating or jacket of Dacron fabric on the implant can be used to support tissue ingrowth. The sensor in Rhodes is recessed within the housing. *See* Rhodes, Figure 2 and page 16, line 13. Furthermore a screen 46 is mounted on the aperture in the case to protect the membrane. *See* Rhodes, Figures 1 and 2; page 14, line 32 to page 15, line 3; page 16, line 14. Accordingly, any coating or jacket of Dacron fabric on the implant disclosed in Rhodes will be prevented from contacting the membrane layers of the sensor (*i.e.*, the screen and housing of the implant will maintain a gap between the sensing portion and the Dacron fabric).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 621, 631 (Fed. Cir. 1987)). Claim 34 recites that the first domain be disposed on at least a portion of the interface tip. One such embodiment is depicted in Figures 1A-C of the instant specification where a sensor interface capsular attachment layer 15 extends over a portion of the sensing dome. In contrast, Rhodes does not disclose a first domain, such as Dacron fabric, extending over the sensing portion of the implant. In fact, the design of Rhodes prevents such an arrangement by placing the sensing portion in a recess and protecting it with a screen. Applicants have developed an improved sensor design that allows tissue ingrowth to come closer to the sensing membrane and

electrodes, thereby improving sensor operation. Because Rhodes does not disclose all limitations of independent Claim 34, Applicants respectfully submit that it does not anticipate Claims 33-36, 48, 54, 70-73, 76-79, and 85-87.

Claim 38 recites, *inter alia*, that "at least a portion of [the] sensing membrane extends beyond the outside of the housing." The instant specification describes the advantage of one such embodiment, noting that "protrusion is believed to assist in the formation of vasculature in the sensor interface dome 30 region." Page 13, lines 20-22. In contrast, as noted above, Rhodes discloses that the sensing region is recessed from the housing. In fact, when Rhodes discloses using an angiogenesis factor to promote capillary formation, it is as a coating on the screen 46, which is separated from the membrane by a gap. Therefore, promotion of vasculature growth in Rhodes is not in the sensing region. The Applicants have developed an improved sensor design that presents the sensing membrane to surrounding tissue and allows close formation of vasculature. Because Rhodes does not disclose "a portion of [the] sensing membrane extend[ing] beyond the outside of the housing," Applicants respectfully submit that it does not anticipate Claims 38-42, 49, 55-58, and 62-65.

Claims 33, 34, 36-42, 48, 49, 54-56, 59, 62-65, 70, 73, 76-79, and 85-87 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gilligan et al. (Diabetes Care, vol. 17, no. 8, 882-888). The Examiner noted that Gilligan discloses a Dacron velour layer over the housing of a glucose sensor. As depicted in Figure 1 of Gilligan, the velour layer covers the exterior of the sensor housing; however, the velour does not contact the dome-shaped sensor. Furthermore, the dome-shaped sensor with membrane layers disposed thereon is positioned within a recess below the outer surface of the housing.

As noted above, Claim 34 recites, *inter alia*, that "[the] first domain is disposed on at least a portion of [the] interface tip." In contrast, Gilligan only discloses Dacron velour covering the outside of the housing. Gilligan concludes that despite the inclusion of the Dacron velour, "maintaining sufficient vascularization immediately adjacent to the sensor for the long term remains a challenge." Gilligan, page 886, column 3 to page 887, column 1. Applicants have developed an improved sensor design that allows the first domain to contact the sensor interface tip, thereby promoting tissue ingrowth closer to the sensing membrane and electrodes. Because Gilligan does not disclose "a first domain...disposed on at least a portion of [the] interface tip,"

the Applicants respectfully submit that Claims 33-37, 48, 54, 70, 73, 76-79, and 85-87 are not anticipated by Gilligan.

As discussed above, Claim 38 recites, *inter alia*, that "at least a portion of [the] sensing membrane extends beyond the outside of the housing." Gilligan only depicts a sensor design where the sensing membrane is seated within a recess below the outer surface of the housing. Accordingly, Applicants respectfully submit that Gilligan does not disclose all the limitations of Claims 38-42, 49, 55, 56, 59, and 62-65, and thus these claims are not anticipated by Gilligan.

Applicants also note that because any Dacron fabric in Rhodes and Gilligan is disposed on the housing and the membranes are recessed from the housing, Rhodes and Gilligan do not disclose a "first domain [being] positioned more distal from [the] housing than [the] second domain" or the "sensing membrane [being] positioned more proximal to [the] housing than [the] second domain." For these additional reason, Claims 33-42, 48, 49, 54-59, 62-65, 70-73, 76-79, and 85-87 are not anticipated by Rhodes or Gilligan.

Rejections under § 103

Claims 37 and 87 have been rejected under 35 U.S.C. § 103(a) as being obvious over Rhodes in view of Gilligan. Claims 59-61, 66-69, 73-75, and 80-83 have been rejected under 35 U.S.C. § 103(a) as being obvious over Rhodes and over Gilligan. Claim 84 has been rejected under 35 U.S.C. § 103(a) as being obvious over Gilligan in view of Allen (U.S. Patent No. 5,322,063). All of the claims rejected under § 103 depend from independent Claims 34 or 38. A *prima facie* case of obviousness requires that all of the claim limitations are taught or suggested by the prior art. *See* M.P.E.P. § 2143.03. As discussed above, neither Rhodes nor Gilligan teach or suggest all limitations found in Claims 34 and 38. Allen does not disclose any of the limitations of Claims 34 and 38 not found in Rhodes or Gilligan. Accordingly, Rhodes, Gilligan, or Allen, or any combination thereof, do not render obvious any claims that depend from Claims 34 and 38. As such, Applicants respectfully submit that Claims 37, 59-61, 66-69, 73-75, 80-84, and 87 are not obvious over the cited art.

CONCLUSION

Based on the foregoing amendments and remarks, the Applicants respectfully submit that they have overcome all pending rejections and request a timely issuance of a Notice of Allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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